

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees:	Ebbehoj et al.	Confirmation No.:	5360
Serial No.:	10/529,858	Art Unit:	1646
371(c) date:	April 26, 2006	Examiner:	G. Chandra
Patent No.:	7,544,657	Customer No.:	21559
Issued:	June 9, 2009		
Title:	STABILIZED EXENDIN-4 COMPOUNDS		

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Patentees note that the patent term adjustment set forth in the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) dated May 20, 2009 in the above-referenced patent appears to be shorter than appropriate.

Patentees submit that the Office has improperly calculated the period for Office delay resulting from failure to issue a patent within the three years of the actual filing date of the application and for failing to apply delays under both 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B). Patentees further submit that the Office also improperly applied a reduction in patent term adjustment for filing a drawing sheet with the Reply to Notice Allowance, a sheet that was filed upon the Office's request. These matters are explained in detail below.

### *Office delay*

Patentees respectfully submit that the Office improperly calculated the three-year delay starting from commence of the national stage in the above-captioned patent and further submit that the Office has failed to apply both the three year delay and the delay in mailing the restriction requirement.

### *Calculation of three-year delay*

Under 37 C.F.R. § 1.702(b), patentees are granted additional patent term for the period starting one day following three years from the actual filing date of the application until issuance of the patent application. For a national stage application, this period is calculated from the day on which the national stage was commenced under 35 U.S.C. § 371(b) or (f). Under § 371(b), the date of national stage commencement begins with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the Patent Cooperation Treaty, which is 30 months from the earliest priority date of the International Application. A different commencement date under § 371(f) applies only if the applicant (a) files an express request for early processing and (b) completes the requirement of § 371(c) prior to the 30-month date.

The present application is the national stage of International Application No. PCT/DK2003/000651, filed October 2, 2003, which claims the benefit of U.S. Provisional Application No. 60/415,626, filed October 2, 2002. The 30-month date under

§ 371(b) is therefore April 2, 2005. Because patentees did not complete the § 371(c) requirements prior to April 2, 2005, the period for adjustment under 37 C.F.R. § 1.702(b) properly begins one day following three years from April 2, 2005, i.e., starting on April 3, 2008.

The delay under 37 C.F.R. 1.702(b) is calculated from three years following national stage commencement until issuance of the patent. The correct Office delay for this period therefore includes the time from April 3, 2008 until June 9, 2009 (date of issuance of the '657 patent), a period of **433** days.

*Calculation of three-year delay in view of other Office delays*

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

\* \* \*

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a) and 1.703(a). Patentees refer to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

\* \* \*

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). Patentees refer to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

**To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap,** the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35

U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, **is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004).

However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added in bold; original emphasis in italics):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

**The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the**

**period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.**

*Wyeth v. Dudas*, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at \*3 (D.D.C. Sep. 30, 2008).

Accordingly, patentees submit that, where no portion of the period of A delay coincides with the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

In the present case, the Office calculated A delay for the period beginning on the day after the date that is fourteen months from the date on which the application fulfilled the requirements of 35 U.S.C. § 371(c) (April 27, 2006) and ending on the date of mailing of an action under 35 U.S.C. § 132 (December 11, 2007). The Office calculated this period as being 168 days, a number which patentees do not dispute.

Because this delay occurred entirely within the three year period following national stage commencement, under the statutory interpretation provided in *Wyeth v. Dudas*, there is no overlap between 168 days of A delay (a period running from June 27, 2007 until December 11, 2007) and the 433 days of B delay (a period running from April 3, 2008 until June 9, 2009).

On this basis, patentees submit that the proper delay calculated under 37 C.F.R. §§ 1.702(a) and (b) is the sum of the A delay (**168 days**) and the B delay (**433 days**), a total of **601 days**.

#### *Applicant delay*

The Office has reduced the period of patent term adjustment for two periods, a reduction of 92 days for failing to respond to an action within three months under 37 C.F.R. § 1.704(b), and for a period of 42 days for providing drawings after mailing a Notice of Allowance under 37 C.F.R. § 1.704(c)(10). Patentees do not dispute the 92 day reduction under 37 C.F.R. § 1.704(b).

Patentees, however, disagree with the application of the 42 day reduction under 37 C.F.R. § 1.704(c)(10). To apply a delay under 37 C.F.R. § 1.704(c), applicants must engage in action or inaction that constitutes “a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application.” The drawing sheet was provided to the Office solely because a Notice to File Corrected Application Papers on April 9, 2009 was issued. Thus inclusion of the drawing sheet with the Reply to Notice of Allowance and Payment of Issue Fee therefore does not constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application, and thus should not result in a reduction of patent term.

Accordingly, Patentees believe the proper period for reduction of patent term adjustment due to applicant delay is **92 days**.

*Total patent term adjustment*

Patentees conclude that the Office delay associated with the '657 patent is 433 + 168 = 601 days, while the applicant delay is 92 days. Thus, the '657 patent is entitled to a total of 601 - 92 = **509** days of patent term adjustment under 37 C.F.R. § 1.703. Patentees request that the patent term adjustment determination be corrected accordingly.

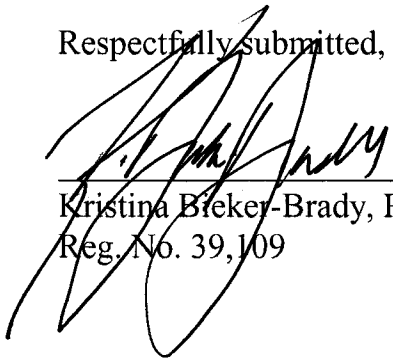
CONCLUSION

Patentees respectfully request that the Office issue a Certificate of Correction indicating the correct patent term adjustment period of 509 days. Transmitted herewith is \$200.00 in payment of the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Date:

August 10, 2009

Respectfully submitted,

  
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